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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,913	02/15/2001	Arthur E. Schulze	2612-001CIP	3079

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EXAMINER

BARBEE, MANUEL L

ART UNIT PAPER NUMBER

2857

DATE MAILED: 10/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/783,913

Applicant(s)

SCHULZE ET AL.

Examiner

Manuel L. Barbee

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-9, 11, 13, 41-43, 46-48, and 50 of copending Application No. 09/860,950. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences in the claims are obvious modifications. Claim 1 of the present application corresponds to claim 1 of the copending application. Claim 1 of the copending application contains all the limitations of claim 1 of the present application except that the sensor is wearable. Since the limitations of the claim 1 of the copending application contains a patient wearable monitoring unit and the sensor is used to acquire data from the patient, it would be obvious for the sensor to be wearable as well. Claims 2-7, 10 and 11 of the present application contain similar limitations to claims 2, 3, 5-8, 11 and 13, respectively of the present application. Claims 8 and 9 of the present application

contain similar limitations to claim 9 of the copending application. Claim 12 of the present application corresponds to claim 41 of the copending application. Claim 41 of the copending application contains all the limitations of claim 12 of the present application except a patient-worn sensor and a second network. It would be obvious to include a patient worn sensor for the same reasons stated above with regard to claim 12. It would further be obvious to include a second network so that devices on different networks could connect. Claims 13 and 14 of the present application contain similar limitations to those of claims 42 and 43 of the copending application. Claim 15 of the present application contains similar limitations to those of claim 46 of the copending application. Claims 16 and 17 of the present application contain similar limitations to those of claim 47 of the copending application. Claim 18 of the present application contains similar limitations to claim 43 of the copending application. Claims 19 and 20 of the present application contain similar limitations to those of claim 48 of the copending application. Claim 21 of the present application contains similar limitations to those of claim 44 of the copending application. Claim 22 of the present application contains similar limitations to those of claim 50 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 7-15 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US Patent No. 5,544,661) in view of Brown (US Patent No. 5,997,476).

With regard to a patient worn sensor connected to a patient worn monitoring unit with a processor, as shown in claims 1 and 12, Davis et al. teach a real time ambulatory patient monitor with an ECG sensor and a plethysmograph sensor connected to a portable monitor that includes a microcontroller (col. 2, line 56 - col. 3, line 22; col. 4, lines 22-39; Figure 1, Figure 5, controller 513). With regard to the monitor having a wireless communication device connected to a first network, a second network and a Host for communicating with the patient monitor, as shown in claims 1 and 12, Davis et al. teach a cellular phone in the patient monitor communicating with the cellular system, the public switched telephone network (PSTN) and a central monitoring and information management system (col. 3, lines 1-22; Figure 1, central station 106, cellular system 104B, PSTN 105). With regard to a terminal means connected to the second network for communicating in a bi-directional manner between a medical care provider and the patient monitor, as shown in claims 1 and 12, Davis et al. teach a clinician that observes data from the patient monitor and communicates with the monitor and the patient (col. 3, lines 15-21; Figure 1, clinician 12). Davis et al. do not teach that either network or the Host is connected to the Internet.

Brown teaches remote monitoring of the physiological condition of a patient and communicating via the Internet (col. 4, lines 24 - col. 5, line 28). Brown teaches the

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alternatives of cellular or telephone networks; however, it is well known to the person having ordinary skill that cellular or telephone networks may be used to connect to the Internet. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the patient monitor, as taught by Davis et al., to include communication via the Internet, as taught by Brown, because then data would have been more accessible on a world wide web server (Brown, column 2, lines 13-50).

With regard to the patient monitoring unit having bi-directional data and voice communication, as stated in claims 2, 3, 7, 13, 14 and 18, Davis teach a the clinician having voice communication with the patient (col. 3, lines 1-22). With regard to the bi-directional data communication comprising instructions to change configurable program instructions, Davis teach that the loading program and setup data to the patient monitor from the central station (col. 5, line 51 - col. 6, line 7, Figure 8, step 802, 803).

With regard to having a microphone and a speaker for the voice communications, as shown in claims 8, 9, 19 and 20, Davis et al. teach a microphone and a speaker (Figure 1, speaker 202B, microphone 202A). With regard to the second network being a PSTN network, as shown in claims 10 and 21, Davis et al. teach a PSTN network (Figure 1, PSTN 105). With regard to the sensor being a biosensor, as shown in claims 11 and 22, Davis et al. teach an ECG sensor and a plethysmograph sensor (Figure 1).

5. Claims 5, 6 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. in view of Brown.

Davis et al. and Brown teach all the limitations of claims 1 and 4 upon which claims 5 and 6 depend and claims 12 and 15 upon which claims 16 and 17 depend.

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Neither Davis et al. nor Brown teach sending instructions to change alarm limits or data collection parameters for at least one sensor, as shown in claims 5, 6, 16 and 17. The Examiner takes official notice that it is well known to send instructions to a remote monitor to change alarm limits or collection parameters. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the patient monitor combination, as taught by Davis et al. and Brown, to include sending instructions to change alarm limits and data collection parameters, because then the patient monitor would be configured more closely to the needs of a particular patient and dangerous conditions would be caught more quickly.

Terminal Disclaimer

6. The terminal disclaimer filed on 9 September 2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,443,890 has been reviewed and is NOT accepted.

7. The application/patent which forms the basis for the double patenting rejection is not identified in the terminal disclaimer. The double patenting rejection is based on Application No. 09/860,940. US Patent No. 6,443,890 is a patent that issued from Application No. 09/516,645.

Response to Arguments

8. Applicant's arguments filed 9 September 2002 have been fully considered but they are not persuasive.

Applicant states that there is no suggestion or motivation to modify Davis et al. or combine it with Brown. Applicant further states that using the Internet for monitoring in

emergency situations would vastly increase costs if done with Davis et al.'s cell phone or limit mobility if the cell phone is replaced with the Internet. Applicant further states that neither Davis et al. nor Brown suggest the desirability of wider patient data accessibility. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the patient monitor, as taught by Davis et al., to include communication via the Internet, as taught by Brown, because then data would have been more accessible on a world wide web server (Brown, column 2, lines 13-50). While the communications cost may increase, accessibility would be increased. Brown teaches a system which allows flexible and dynamic querying of the patients (col. 2, lines 36-38). Davis et al. teach the desire to monitor with a patient outside of a hospital (col. 1, lines 12-60). Monitoring high risk cardiac patients would require a certain degree of data accessibility. While the use of cellular phones and land line phones, as taught by Davis et al, increases accessibility, the inclusion of an Internet connection allowing data to be logged and reviewed by the patient and the medical provider, as taught by Brown increases data accessibility and convenience.

Applicant states that the claimed invention has a triangular network architecture and that neither Davis et al. nor Brown teach or fairly suggest such an architecture. The claimed invention shows a connection between a first wireless network, a second network and the Internet. Davis et al. teach a cellular phone in the patient monitor communicating with the cellular system, the public switched telephone network (PSTN) and a central monitoring and information management system (col. 3, lines 1-22; Figure 1, central station 106, cellular system 104B, PSTN 105). The cellular network is a

wireless network and the PSTN network is the second network. Brown teaches remote monitoring of the physiological condition of a patient and communicating via the Internet (col. 4, lines 24 - col. 5, line 28). The Internet connects to both the cellular network and the PSTN network.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Bardy (US Patent No. 6,398,728) teaches an automated collection and analysis patient care system.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel L. Barbee whose telephone number is 703-308-0979. The examiner can normally be reached on Monday-Thursday from 7-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on 703-308-1677. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7722 for regular communications and 703-308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-0976.

mlb
October 9, 2002


MARC S. HOFF
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800